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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,373	11/19/2003	Ortrud K. Steinlein	50316/004002	7699

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EXAMINER	
HAMA, JOANNE	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,373	STEINLEIN ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application, filed November 19, 2003, claims priority to U.S. Provisional Application, 60/489,271, filed July 21 2003 and to foreign application, 102 54 652.5, filed November 22, 2002, in Germany.

Applicant filed amendments to the claims May 6, 2004.

Claims 1-20 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 17, drawn to a transgenic non-human animal comprising a missense mutation in the α4 or β2-subunit of the neuronal nicotinic acetylcholine receptor (nAChr), classified in class 800, subclass 13.

II. Claims 6-11 and 18, drawn to a targeting vector comprising a nucleic acid sequence encoding a subunit of a human or murine nicotinic acetylcholine receptor (nAChr) having a missense mutation in the α4- or β2- subunit or part of said subunit, wherein said part comprises at least said missense mutation in the α4- or β2- subunit operably linked to a selectable marker, and to a stem cell comprising the vector, classified in class 536, subclass 23.1.

III. Claims 12, 13, 19, and 20, drawn to a screening method for the identification of compounds for the treatment of human epilepsy, comprising the steps of: a) providing an animal of claim 1, b) administering said test compound to said animal, and c) selecting a test compound that

alleviates or eliminates symptoms of an epilepsy syndrome in said animal, classified in class 800, subclass 3.

IV. Claims 14-16, drawn to a compound and a pharmaceutical composition for the treatment of human epilepsy syndrome, and to a method for treating a human epilepsy syndrome, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct. While the targeting vector constructs could be used to generate the transgenic non-human animals of Invention I, the targeting constructs could also be used in cultured cells. The searches for Invention I and II are burdensome because the searches are not coextensive.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the transgenic non-human animal of Invention I can be used as a model system to study AchR gene function.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I is drawn to a transgenic non-human mammal comprising a

missense mutation in the α4 or β2-subunit of the neuronal nicotinic acetylcholine receptor (nAChr). Invention IV is to a compound and a pharmaceutical composition for the treatment of human epilepsy syndrome and to a method for treating a human epilepsy syndrome. While there may be a relationship between Inventions I and IV in that the transgenic non-human animal could be used to in a method of screening for compounds used to treat human epilepsy syndrome, the transgenic non-human animal of Invention I is structurally different from the compound and pharmaceutical composition of Invention IV. Further, the transgenic non-human mammal is not used in the method of treating and is thus independent of the method. Invention I does not depend on Invention IV to function and vice versa.

Inventions II and III are patentably distinct. While Invention II is used to generate the transgenic non-human animal of Invention I, upon which, Invention III depends, the targeting construct of Invention II can be used in other applications, such as in cell culture. The searches for Inventions II and III are burdensome because the searches are not coextensive.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II is drawn to a targeting vector and Invention IV is drawn to a compound, a pharmaceutical composition for the treatment of epilepsy, and to a method of treating human epilepsy syndrome. Invention II does not depend on Invention IV to function, and vice versa.

Inventions III and IV are patentably distinct. While Invention IV is obtained from the method of Invention III, the compound of Invention IV can be identified using other assays (e.g. in vitro) and does not require the animal of Invention I. The search for Invention III and IV is burdensome because the searches are not coextensive.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and the search for one Invention is not required for the search of another, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

The transgenic non-human animal of Inventions I-III is drawn to a plurality of missense mutations. The missense mutations are:

1. V287L,
2. V287M,
3. 259-260ins,
4. S252L,
5. 766ins3,
6. T265I.

The compound, pharmaceutical composition, and method for treating human epilepsy syndrome of Invention IV are drawn to a plurality of compounds. The compounds are:

a. barbiturates,

b. oxazolidindiones,

c. succinimides,

d. derivatives of benzodiazepines,

e. sultiam,

f. Carbamazepin,

g. valproic acid,

h. the compound of formula I, wherein R1 and R2 are alkyl or aryl residues and R3 is H or an alkyl residue. Should the Applicant elect species h, the compound of formula I, the Applicant must state one residue corresponding to each R group.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5 and 17 are generic for the transgenic animal comprising a missense mutation; claims 6-11 and 18 are generic for the targeting construct comprising a nucleic acid sequence encoding an acetylcholine receptor having a missense mutation in the α4- or β2-subunit; and claims 14-16, 19, and 20 are generic for compound or pharmaceutical composition that treats human epilepsy.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER